May 11, 2001

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Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852

Re: FDA Docket 98P-0610

I am a member of the public writing with regard to the petition to grant non-prescription status to the allergy medications Allegra, Claritin, and Zyrtec. I would ask that my comments be made part of the formal record in this matter, and be considered by the FDA in making its decision.

I would urge the FDA to make this decision entirely on the medical merits of whether or not these medications are suitable for over-the-counter use, and to disregard claims as to an economic right to prescription status that have reportedly been made by their manufacturers.

Four of our five family members suffer significant seasonal allergies. Access to non-sedating allergy medications is important to us. At present, our health plan (Kaiser Permanente) provides these medications as part of our health coverage, including subsidizing the price of the prescription. However, non-prescription status for these medications would be more helpful, because at present we can only obtain prescriptions with a doctor's permission (although refills are somewhat streamlined), and because having a prescription filled is less convenient than buying over-the-counter medicine. In particular, this process has hampered us in finding the right medication for each family member, since each new trial of a different medicine requires a doctor's participation. After some experimentation, we have found that some of us respond well to Allegra while others do not, and that one of us can use Claritin. The next logical step is to try Zyrtec, but it will presumably take some time and effort to get appropriate prescriptions and have them filled.

As consumers, we also recognize that there is no free lunch. Our health care costs come out of my salary, and the fact that a prescription price is subsidized must be reflected in the cost of health care. Ultimately, consumers and taxpayers must pay the cost of these



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drugs. Higher prices and less accessibility are thus harmful to our family, if there is no legitimate medical reason for them. Also, there is a significant loss to the public interest if doctors and their staff must spend time dealing with writing prescriptions for medications for which they are not medically necessary. Such time and effort misspent simply amount to waste in our health care system.

I have also read that at least some, and perhaps all of these medications are apparently sold over-the-counter in some other countries. I would encourage the FDA to consider the experience in those countries in evaluating predictions that have been made in other comments as to possible medical harm if the petition is granted.

Finally, I would urge the FDA to reject any theory that may be proposed to suggest that an economic right exists for the manufacturer in the prescription status of a medication. Prescription status should be used only as necessary to protect the public health, and the fact that an economic value may inadvertently be created by prescription status is no good reason to perpetuate it. By contrast, the patent process is appropriately intended to promote innovation by creating a limited monopoly property right, and I understand that some or all of these medications may be patented. The patent process should satisfy any legitimate claim of these firms to added profits through governmental protection.

Thank you for considering my comments and concerns in this matter.

Sincerely,

Carl Danner
215 Via Bonita
Alamo, CA 94507

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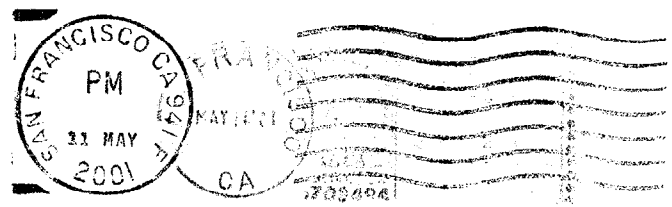


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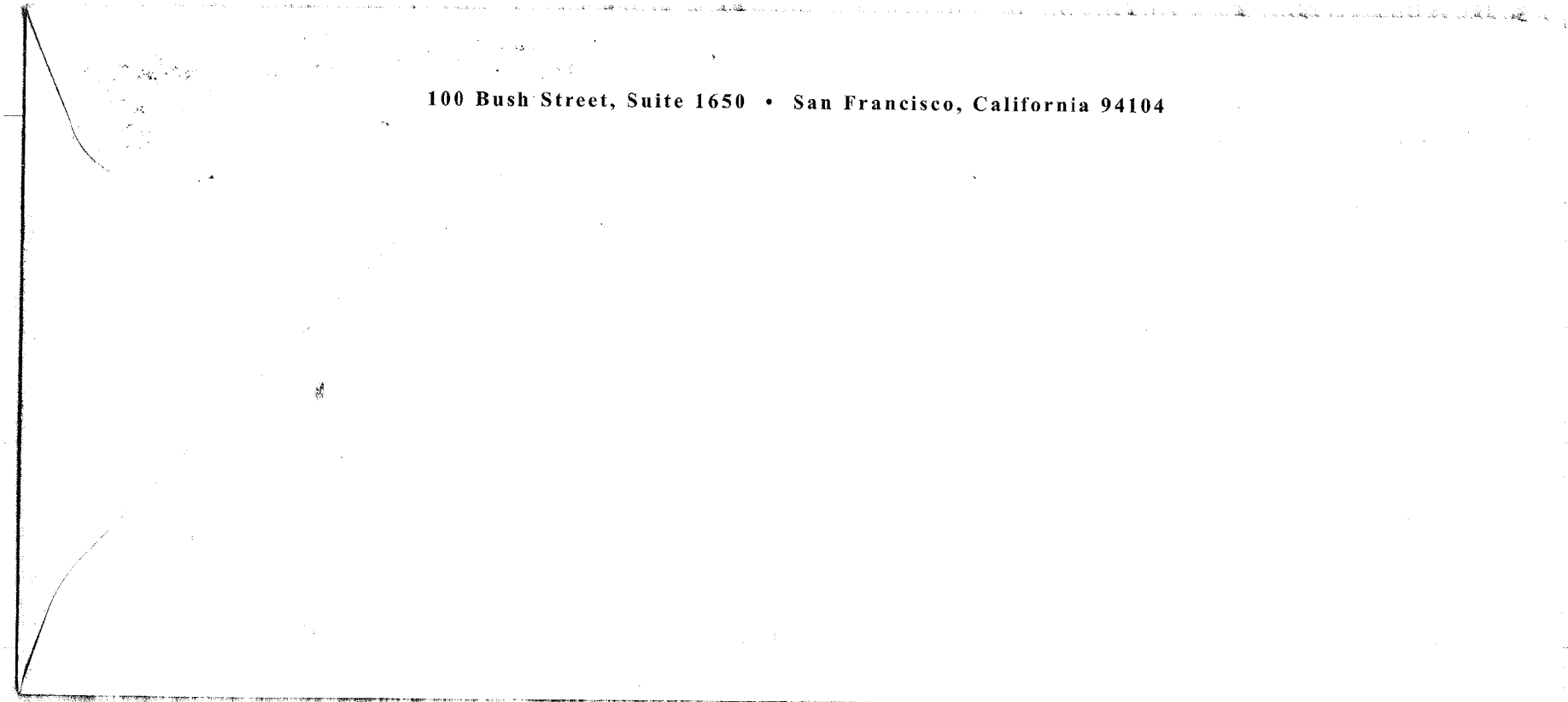

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